K022251

AUG 0 6 2002

4 Summary of Safety and Effectiveness

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS for SAFE MAXI venous/cardiotomy reservoir as required by section 807.92(c).

Submitter's Information:

Name:	POLYSTAN A/S
Address:	Walgerholm 8, 3500 Værløse, Denmark
Phone:	+ 45 44 65 15 66
Fax	+ 45 44 68 15 66
Contact person:	Dana Olsen, Regulatory Affairs
Date of preparation:	July 10, 2002

Device name:

Trade Name:	SAFE MAXI venous/cardiotomy reservoir
Common/Usual name:	blood reservoir
Classification name:	Cardiopulmonary bypass blood reservoir (21 CFR – 870.4400) Cardiopulmonary bypass defoamer (21 CFR – 870.4230) Cardiopulmonary bypass cardiotomy suction line blood filter (21 CFR- 870.4270)

Predicate Device Name(s):

SAFE MINI oxygenator with venous/cardiotomy reservoir - 510(k) no. K980974
Gish Biomedical Cardiotomy/Venous Reservoir 510 (k) no. K883923

Device Description:

SAFE MAXI venous/cardiotomy reservoir is a hard shell reservoir with separate venous and cardiotomy inlets. The venous inlet with 175 micron venous filter is placed at the bottom of the reservoir, which provides a bottom to top venous blood flow. Returning suction blood enters the large surface area 20 micron depth filter at the top of the reservoir.

The SAFE MAXI venous/cardiotomy reservoir is single-use, disposable, sterile and non-pyrogenic. The reservoir is a sealed type for vacuum applications. The maximum capacity of the reservoir is 4000 ml.

Intended Use:

The SAFE MAXI venous/cardiotomy reservoir is intended for use with an oxygenator in an extracorporeal circuit to store venous return blood and to defoam and filter intra-thoracic suction blood prior to returning it to the extracorporeal circuit.

Technological Characteristics Summary:

- Biocompatibility and Blood Cell Damage Testing:
  The SAFE MAXI venous/cardiotomy reservoir has similar design characteristics and material content as the SAFE MINI reservoir K980974 except that the reservoirs differ in size. Based on the biocompatibility testing performed on the SAFE MINI (the predicate device), the SAFE MAXI was determined to be biocompatible and non-toxic, therefore, safe for its intended use.

  Blood cell damage test of the SAFE MAXI reservoir and the Gish Biomedical reservoir were performed using the same blood pool.

- Effectiveness Testing:
  The function of the SAFE MAXI reservoir was determined by evaluating its operational characteristics.

Conclusion:

The biocompatibility, performance, and function test data demonstrated that the SAFE MAXI reservoir is substantially equivalent to the predicate devices SAFE MINI reservoir (K980974) and Gish Biomedical Cardiotomy/Venous Reservoir (K883923).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 6 2002

Polystan A/S
c/o Ms. Dana Olsen
Regulatory Affairs
8, Walgerholm
DK-3500 Vaerlose
DENMARK

Re: K022281
Trade Name: SAFE MAXI Venous/Cardiotomy Reservoir
Regulation Number: 21 CFR 870.4400, 870.4230, and 870.4270
Regulation Name: Cardiopulmonary Bypass Blood Reservoir/Defoamer and Suction Line Blood Filter
Regulatory Class: Class II (two)
Product Code: DTN
Dated: July 10, 2002
Received: July 15, 2002

Dear Ms. Olsen:

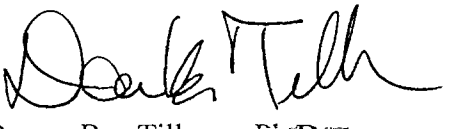
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3 Indication for Use

Statement of Indication for Use

The SAFE MAXI venous/cardiotomy reservoir is intended for use with an oxygenator in an extracorporeal circuit to store venous return blood and to defoam and filter intra-thoracic suction blood prior to returning it to the extracorporeal circuit.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022287

Prescription Use X OR Over-The-Counter Use __